REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated January 3, 2006 are respectfully requested. Applicants petition the Commissioner for a 3-month extension of time. A separate petition accompanies this amendment.

I. Rejection under 35 U.S.C. §112, first paragraph

Claim 7 was rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner objected to the language "by volume." The Examiner is respectfully directed to paragraph [0075] of the published application where "volume percentages" of ethanol are tested. Thus, the language "percent by volume" finds basis in the application as filed.

In light of the above, Applicants submit that the present claims satisfy the requirements of 35 U.S.C. §112, first paragraph and respectfully request that the rejections be withdrawn.

II. Rejections under 35 U.S.C. §102

Claims 1-2 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Kunz *et al.* (U.S. Patent No.). This rejection is respectfully traversed.

A. The Present Application

The present claims describe a method of forming a coating having a selected surface density of a selected chemical group on the surface of a substrate. The method comprises the steps of:

(a) exposing the surface of the substrate to a plasma within a plasma chamber maintained substantially at atmospheric pressure, to form one or more

active species on said substrate surface, until a desired surface density of the active species is formed;

(b) in the absence of exposure to plasma, exposing the surface to a selected gas or liquid under conditions effective to convert the active species to a stable functional group; and

(c) optionally contacting the exposed surface to a surface-modifying group under conditions effective to covalently attach the surface-modifying group to said functional group,

where the selected chemical group on the surface is the stable functional group or the surface-modifying group covalently attached thereto.

B. The Cited Art

KUNZ ET AL. disclose a process for the production of a strongly adherent coating. The process includes subjecting the substrate to a low-temperature plasma discharge (among others). The substrate is precoated with at least one electron or hydrogen donor compound with at least one ethylenically unsaturated group and reacted with the free radicals formed there. The substrate is then coated with a composition comprising at least one ethylenically unsaturated monomer or oligomer and cured.

C. Analysis

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

The presently claimed method of forming a coating on the surface of a substrate includes a step of exposing the surface to a selected gas or liquid under conditions effective to convert the active species (formed by plasma deposition) to a stable functional group in the absence of exposure to plasma. Kunz *et al.* fail to teach this claimed step. Instead, the method of Kunz et al. includes subjecting a substrate to a low temperature plasma discharge, applying a coinitiator of an

electron- or H-donor, coating the substrate with a composition, and curing the coating. The step of applying a coinitiator does not create a stable functional group as in the present claims. This electron- or H-donor is an unstable reactive group. The method of Kunz et al. requires four-steps to produce a stable functional group. In contrast, the present method provides a stable functional group in two steps.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. §102 has not been met. Withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

III. Rejections under 35 U.S.C. §103

Claims 1-9, 21-26 and 29-31 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Ikada *et al.* (U.S. Patent No. 4,743,258) in view of Yializis *et al.* (U.S. Patent No. 6,118,218) or Krause *et al.* (U.S. Patent No. 5,500,257).

Claims 1-2, 5, 7, 25-26, and 29-31 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Gudimenko *et al.* (U.S. Patent App. No. 2003/0021996A1) in view of Yializis *et al.*

Claims 1-2, 5-7 and 25 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over O'Brien (U.S. Patent No. 6,709,718) in view of Yializis *et al.* or visa versa.

Claims 7 and 25 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kunz *et al.*

Claims 1-5, 7-10, 12, 20-24, 26, and 29-30 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Subramaniam (U.S. Patent No. 5,643,580) in view of Yializis *et al.*

Claims 13-15 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Subramaniam (U.S. Patent No. 5,643,580) in view of Yializis *et al.*, and further in view of Valentini or Clapper.

A. The Present Application is described above.

B. The Cited Art

KUNZ ET AL. is described above.

IKADA ET AL. disclose a blood-compatible material that includes a polymeric base material and water-soluble and substantially nonionic polymers directly attached to the surface of the base material. The polymers may be attached by forming radicals or peroxides on the surface of the base material and contacting the monomer(s) with the base. The radicals or peroxides may be formed by i.e. low-

temperature plasma discharge. Nowhere does Ikada *et al.* show or suggest exposing a substrate surface to a selected gas or liquid under conditions effective to convert the active species to a stable functional group.

YIALIZIS ET AL. disclose an apparatus for producing a glow-discharge plasma at substantially atmospheric pressure comprising a pair of opposing electrodes, at least one of the electrodes comprising a metallic porous layer.

KRAUSE ET AL. describe a method of preparing a fluoropolymer composite tube for use in gas lines. The tube is prepared by activating a formed fluoropolymer substrate by subjecting the substrate to a charged gaseous atmosphere formed by electrically ionizing a gas and subsequently applying a layer of a thermoplastic polymer to the activated fluoropolymer. The ionizing step may be a corona discharge or electrically formed plasma. Nowhere does Krause *et al.* show or suggest exposing a substrate surface to a selected gas or liquid under conditions effective to convert the active species to a stable functional group, in the absence of exposure to plasma.

GUDIMENKO ET AL. disclose a process for the production of solid polymeric or composite substrates having surfaces with enhanced release properties. The process includes surface activation of the solid substrate wherein reactive hydrogen groups are formed in the sub-surface region of the substrate. The activated surface is then activated with a silyation solution such that substantially all of the reactive hydrogen groups formed by the activation step are replaced by silicon-containing groups.

O'BRIEN relates to a method for surface treating a porous sheet material. The porous sheet material is contacted with plasma at atmospheric pressure.

SUBRAMANIAM describes biocompatible coatings for medical devices. Plasma is used to functionalize the surface of the medical device with reactive groups. The functionalized surface is then contacted with a bioactive agent or Langmuir-Blodgett film, which is thermochemically covalently coupled to the reactive groups to form the coating.

VALENTINI discloses implantable prosthetic devices having a gold layer on the surface to which bioactive molecules are attached. The device is coated with gold by evaporation, electroplating, sputtering, or electrodeposition. The bioactive molecule is then attached to the gold using "simple chemistry techniques." Molecule coated polymer surfaces (FEP) were also prepared as a control. In this method, surface hydroxyl groups were added to cleaned FEP films by RF glow discharge under pressure. The peptides were rinsed and a peptide was then coupled to the hydroxyl groups. That is, the hydroxyl groups produced by glow discharge form the stable function groups to which the peptides are attached. Nowhere does this reference show or suggest first forming active species on the surface of a substrate, then, in the absence of exposure to plasma, exposing a substrate surface to a selected gas or liquid under conditions effective to convert the active species to a stable functional group.

CLAPPER discloses a porous material having a surface chemistry that promotes capillary endothelialization. The material has a porosity that is sufficient to allow capillary endotheliazation. Clapper further discloses binding a cell adhesion molecule to promote ingrowth of endothelial cells into the pores of the material. Nowhere does Clapper show or suggest exposing a substrate surface to a selected gas or liquid under conditions effective, and in the absence of exposure to plasma, to convert an active species formed during plasma treatment to a stable functional group.

C. Analysis

According to the MPEP § 2143, one of the three basic criteria to establish a *prima facie* case of obviousness is that the prior art references (or references when combined) must teach or suggest all the claim limitations.

1. Rejection over Ikada et al. in view of Yializis et al. or Krause et al.

As noted above, the presently claimed method includes a step of exposing the surface to a selected gas or liquid under conditions effective to convert the active species (formed by plasma deposition) to a stable functional group in the absence of exposure to plasma. None of the references show or suggest this claimed step.

As described in Example 2, Ikada *et al.* teach treating a film with a corona discharge and them immersing the corona treated film in an aqueous solution containing a water-soluble and substantially non-ionic polymer. According to the Office action mailed April 2005, converting the active species to a stable functional group "may be considered to occur after the corona discharge due to normal exposure to air before the immersion step." However, the active groups are used to react with the polymer and thus cannot be stabilized prior to immersion. Converting the active species to a stable functional group is not an instantaneous reaction and thus, exposure to air for a short period of time would not fulfill the requirements of the method as claimed. Thus, Ikada et al. cannot be relied upon for a teaching of converting the active species to a stable functional group as the active species are required to react with the polymer.

Yializis *et al.* is cited for a teaching of an atmospheric plasma treater to force diffusion of the plasma medium through the porous structure of a porous-metal electrode. Yializis *et al.* fail to make any mention of exposing the surface of a substrate to plasma at atmospheric pressure to form one or more active species on a substrate surface and converting the active species to a stable functional group in the absence of exposure to plasma.

Krause *et al.* teach activating a fluoropolymer substrate by subjecting the substrate to a charged gaseous atmosphere. A layer of a thermoplastic polymer is then applied to the activated fluoropolymer. Nowhere does Krause *et al.* disclose stabilizing the active groups formed on the substrate. Nor would one stabilize these groups as they are necessary to bind to the thermoplastic layer, a necessary feature of Krause *et al.*

The combination of the teaching in Ikada et al., Yializis et al., and Krause et al. fails to teach a step of converting active groups on a substrate to a stable functional group. Instead, each of the groups teach reacting the active group with a compound of interest. If one were to convert the active group to a stable functional group, the compound of interest would not bind to the substrate through the active group.

2. Rejection over Gudimenko et al. in view of Yializis et al.

As discussed above, the claimed method includes a step of exposing the substrate surface to a selected gas or liquid under conditions effective to convert the active species (formed by plasma deposition) to a stable functional group in the absence of exposure to plasma.

Gudimenko *et al.* teach formation of reactive hydrogen groups in a surface region of a solid substrate by corona discharge treatment in air at atmospheric pressure. The reactive groups are then reacted with a silyating agent such that substantially all of the reactive hydrogen groups formed by the activation step are replaced by silicon-containing groups (paragraphs 0027-0030). Thus, the reactive hydrogen groups are replaced by silicon-containing groups and cannot be stabilized prior to contact with the silicon-containing groups.

Nor would one be motivated to modify the teaching in Gudimenko *et al.* to stabilize the reactive hydrogen groups as they are necessary for replacement with the silicon-containing groups, a necessary feature of Gudimenko *et al.*

As noted above, Yializis *et al.* also fail to show or suggest a step of converting the active species to a stable functional group.

3. Rejection over O'Brien in view of Yializis et al. or visa versa

As noted above, the presently claimed method includes a step of exposing the surface to a selected gas or liquid under conditions effective to convert the active species (formed by plasma deposition) to a stable functional group in the absence of exposure to plasma. Neither of the references show or suggest this claimed step.

O'Brien teaches treatment of a porous film with plasma gas to penetrate into the pores and react with the interior surfaces of the pores to make the film more hydrophilic. O'Brien makes no mention of forming one or more active species on a substrate surface and subsequent exposure to convert the active species to a stable functional group. Instead, the plasma treatments "are believed to generate oxygen containing functional groups" on the film surface. These functional groups are generated directly on the film in the presence of the plasma rather than first generating active species with the plasma and converting the active species to stable functional groups in the absence of plasma as presently claimed.

As noted above, Yializis *et al.* also fail to show or suggest converting the active species to a stable functional group.

4. Rejection over Kunz et al.

Kunz *et al.* teach activating a substrate by low-temperature plasma discharge. The substrate is then precoated with an electrode or hydrogen donor coinitiator compound. Nowhere does Kunz *et al.* disclose stabilizing the active groups formed on the substrate. Nor would one stabilize these groups as they bind to the coinitiator, a necessary feature of Kunz *et al.*

Nor would one be motivated to modify the teaching in Kunz *et al.* to stabilize the ethylenically unsaturated group as they bind to the coinitiator, a necessary feature of Kunz *et al.*

5. Rejection over Subramaniam in view of Yializis et al.

As noted above, the presently claimed method includes a step of exposing the surface to a selected gas or liquid under conditions effective to convert the active species (formed by plasma deposition) to a stable functional group in the absence of exposure to plasma. None of the references show or suggest this claimed step.

As described at Col. 2, lines 56-58 and Col. 3, lines 22-24 and 31-33, Subramaniam teaches functionalizing the surface of a medical device by contacting the surface with plasma to form chemically reactive groups. These reactive groups are then contacted with a bioactive agent to covalently bind the agent to the surface by thermochemical reaction with the surface reactive groups. Thus, the reactive groups are used to react with the bioactive agent and cannot be stabilized prior to contact with the agent. Nor would one be motivated to modify the teaching in Subramaniam to stabilize the reactive groups as they are thermochemically reacted with the bioactive agent, a necessary feature of Subramaniam.

Yializis *et al.* is cited for a teaching of an atmospheric plasma treater to force diffusion of the plasma medium through the porous structure of a porous-metal electrode. Yializis *et al.* fail to teach forming one or more active species on a substrate surface and exposing the surface of a substrate to plasma at atmospheric under conditions to convert the active species to a stable functional group in the absence of exposure to plasma.

6. Rejection over Subramaniam in view of Yializis et al., and further in view of Valentini or Clapper

The deficiencies in the combination of Subramaniam and Yializis *et al.* are discussed above.

The Valentini and Clapper references are cited merely for a teaching of the cell-adhesion molecule disclosed in claims 13 and 15. Neither Valentini nor Clapper make up for the shortcoming in the combination of Subramaniam in view of Yializis *et al.*, as discussed above, as neither reference makes any mention of

exposing the substrate surface to a selected gas or liquid to convert the active species to a stable functional group.

As shown above, none of the references, alone or in combination, show or suggest exposing the substrate surface to a selected gas or liquid under conditions effective to convert the active species to a stable functional group. Instead, the references generally teach exposing the surface of a substrate to plasma to form active species that are then reacted with a compound of interest to bind the compound to the substrate via the reactive species. None of the references teach forming active species and then converting them to stable functional groups. In fact, to do so would render the methods of the cited references inoperable as the compounds would not bind to the reactive groups. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103.

IV. Obvious-Type Double Patenting Rejections

Claims 1-10, 12, 21-23, 26, and 29-31 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-8 and 11-17 of U.S. Patent No. 6,159,531 in view of Yializis *et al.*, and further in view of Ikada *et al.*.

Claims 13-15 and 20 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-8 and 11-17 of U.S. Patent No. 6,159,531 in view of Yializis *et al.*, in view of Ikada *et al.*, and further in view of Valentini or Clapper.

Applicants respectfully traverse these rejections.

A. The Present Application

As noted above, the present claims include the steps of:

(a) exposing the surface of the substrate to a plasma within a plasma chamber maintained substantially at atmospheric pressure, to form one or more

active species on said substrate surface, until a desired surface density of the active species is formed;

(b) in the absence of exposure to plasma, exposing the surface to a selected gas or liquid under conditions effective to convert the active species to a stable functional group; and

(c) optionally contacting the exposed surface to a surface-modifying group under conditions effective to covalently attach the surface-modifying group to said functional group,

where the selected chemical group on the surface is the stable functional group or the surface-modifying group covalently attached thereto.

B. The 6,159,531 Patent

The claims in Patent No. 6,159,531 relate to a method of treating a medical device briefly comprising:

plasma cleaning the device surface exposed to tissue and/or blood;

functionalizing the surface to provide a plasma-deposited layer having functional groups; and

subjecting the plasma-deposited layer to multifunctional linkers/spacers to form covalent bonds between the linkers/spacers and the functional groups.

C. Analysis

The method of the present invention includes a step of exposing the surface to a selected gas or liquid under conditions effective to convert the active species to a stable functional group in the absence of exposure to plasma.

While the method of the '531 patent provides a plasma-deposited layer having functional groups and subjects the layer to multifunctional linkers/spacers to form covalent bonds between the linkers/spacers and the functional groups (optional in the present claims), the '531 patent makes no mention of an intermediate step of converting the active species to a stable functional group, much less converting the active species in the absence of exposure of plasma.

Nor do the cited Beumer *et al.*, Maruyama *et al.*, Li *et al.*, Ikada *et al.* ('258), Krause *et al.*, or Ikada *et al.* ('913) references make up for this lack of teaching for the reasons given above in section III.

In view of the above, Applicants submit that the invention as presently claimed is patentably distinct from U.S. Patent No. 6,159,531. Accordingly, Applicants respectfully request withdrawal of the rejection under the judicially created doctrine of obviousness-type double patenting.

D. Answer to Arguments

Applicants respectfully request an answer as to the arguments presented with traversal of the Obviousness-Double Patenting rejections, repeated herein. According to M.P.E.P. § 707.07(f), "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it."

V. Conclusion

In view of the foregoing, Applicants submit that the claims pending are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,

Date: July 3, 2006

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